

***Remarks***

Reconsideration of this Application is respectfully requested.

The Examiner has allowed claims 34 to 50. Claims 27 and 52 are sought to be amended, and claim 51 is sought to be cancelled without prejudice to or disclaimer of the subject matter therein. Upon entry of the foregoing amendment, claims 27, 30-50 and 52 are pending in the application, with 27, 34, 39 and 45 being the independent claims. Support for the amendment to claims 27 and 52 can be found in the originally filed claims and throughout the specification. *See, e.g.*, page 9, last line to page 10, line 2; and page 15, lines 16-21. These changes are believed to introduce no new matter, and their entry is respectfully requested.

Based on the above amendment and the following remarks, Applicants respectfully request that the Examiner reconsider all outstanding objections and rejections and that they be withdrawn.

***Finality of Office Action***

Upon further consideration, the Examiner withdrew the finality of the previous Office Action dated March 11, 2003. (*See* Office Action, page 2, ¶ 1.) As a Notice of Appeal was filed by Applicants on August 11, 2003, along with the associated fee of \$160.00, Applicants are filing a Request for Refund herewith in accordance with the Examiner's suggestion.

***Rejections under 35 U.S.C. § 112, First Paragraph***

Applicants thank the Examiner for the withdrawal of the rejection of claims 27 and 30-33 under 35 U.S.C. § 112, first paragraph. (See Office Action, page 2, ¶ 2.)

***Rejections under 35 U.S.C. § 103***

Applicants thank the Examiner for the withdrawal of the rejection of claims 27 and 30-33 under 35 U.S.C. § 103(a). (See Office Action, page 2, ¶ 3.)

***Rejections under 35 U.S.C. § 112, First Paragraph***

The Examiner rejected claims 27, 30 to 33 and 51 under 35 U.S.C. § 112, first paragraph, as allegedly "failing to comply with the written description requirement." (Office Action, page 2, ¶ 4.) In particular, it is the Examiner position that

[t]hese claims are drawn to methods of treatment involving interleukins. Unlike the interferon, interleukins are a structurally and functionally diverse family. Not all of the members of this family are anti-inflammatory . . . . Applicants has provided no characteristics by which one of skill in the art could identify anti-inflammatory interleukins. While the art identifies several, it also fails to describe any characteristics that would identify a genus of such molecules.

(Office Action, pages 2-3, ¶ 4.) Applicants respectfully traverse this rejection as it may apply to the present claims.

Applicants note that claim 51 has been cancelled. Further, claim 27 has been amended and is currently directed to a method of treating inflammatory disease in a patient comprising administering to a patient a therapeutically effective amount of a fusion protein comprising a latency associated peptide and a proteolytic cleavage site, wherein the fusion protein is covalently linked to an interleukin selected from the group consisting of

interleukin-4, interleukin-5, interleukin-6, interleukin-10, interleukin-11, interleukin-12 and interleukin-13 and wherein the fusion protein is heterologous to the interleukin.

Applicants submit that each of the members of the claimed genus of interleukins has anti-inflammatory activity. Moreover, such anti-inflammatory activity has been confirmed by the art. For example, the anti-inflammatory activity of interleukin-4, interleukin-6, interleukin-10, interleukin-11 and interleukin-13 has been confirmed in Opal and DePalo, *Chest* 117:1162-1172 (2000) (Exhibit A). See Table 1. The anti-inflammatory activity of interleukin-5 has been confirmed in Han *et al.*, *Am. J. Respir. Cell Mol. Biol.* 21:303-310 (1999) (Exhibit B) as well as in Wiesemann *et al.*, *Clin. Exp. Immunol.* 133:454-460 (2003) (Exhibit C).<sup>1</sup> The anti-inflammatory activity of interleukin-12 has been confirmed in Bryan *et al.*, *Lancet.* 356:2149-53 (2000) (Exhibit D).

In view of the above, Applicants submit that the claimed invention complies with the written description requirement of 35 U.S.C. § 112, first paragraph. Accordingly, Applicants respectfully request that this rejection be withdrawn.

### ***Objection to the Claims***

The Examiner objected to claim 52 as being dependent upon a rejected base claim, but indicated that it would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. (Office Action, page 3, ¶ 5.)

Applicants submit that amended claim 27, from which amended claim 52 is directly dependent, is allowable. As such, Applicants submit that the basis for the objection has been removed and request that the Examiner withdraw the objection.

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<sup>1</sup>The characterization of interleukin-13 as an anti-inflammatory cytokine is also referred to on page 458, col. 2, second full paragraph of Wiesemann *et al.*

***Allowed Claims***

Applicants thank the Examiner for indicating the allowance of claims 34 to 50.

***Conclusion***

All of the stated grounds of objection and rejection have been properly traversed, accommodated, or rendered moot. Applicants therefore respectfully request that the Examiner reconsider all presently outstanding objections and rejections and that they be withdrawn. Applicants believe that a full and complete reply has been made to the outstanding Office Action and, as such, the present application is in condition for allowance. If the Examiner believes, for any reason, that personal communication will expedite prosecution of this application, the Examiner is invited to telephone the undersigned at the number provided.

Prompt and favorable consideration of this Amendment and Reply is respectfully requested.

Respectfully submitted,

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